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Information required for dossiers to support demands for import of high risk plants, plant products and other objects as foreseen in Article 42 of Regulation (EU) 2016/2031

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Abstract

Article 42 of the new Plant Health Law (Regulation (EU) 2016/2031 on protective measures against pests of plants), introduce a concept of "high risk plants, plant products and other objects" in relation to the presence of a pest risk of an unacceptable level for the Union territory, identified on the basis of a preliminary assessment to be followed by a risk assessment. Upon request of the European Commission (EC), the European Food Safety Authority (EFSA) defined the information required and developed a format for the preparation and submission of technical dossiers from third countries to support demands for import of high risk plants, plant products and other objects as foreseen in Article 42(5) of Regulation (EU) 2016/2031. The draft of this Technical Report was circulated to the EFSA Scientific Network for Risk Assessment in Plant health for commenting. The aim of this Technical Report is to enable the applicants to provide in their technical dossiers the information needed by EFSA to perform a Commodity Risk Assessment. The information required concerns: 1) the commodity (characterization of product and the description of the production process); 2) the pests potentially associated with the commodity in the exporting country; 3) the data on phytosanitary mitigation measures and inspections. Instructions on how this information should be presented are also provided.

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Keywords: commodity risk assessment, third country, European Union, plants for planting, wood, fruit, phytosanitary mitigation measure.

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1. Introduction

1.1. Background as provided by the European Commission

Regulation (EU) No 2016/2031¹, on the protective measures against pests of plants, will be applying from December 2019. Provisions within the above Regulation are in place for the listing of "high risk plants, plant products and other objects" (Article 42) on the basis of a preliminary assessment, and to be followed by a risk assessment. A first list of "high risk plants, plant products and other objects" is to be adopted by end 2018. Scientific opinions are therefore needed to support the European Commission and the Member States in the work connected to Article 42 of Regulation (EU) No 2016/2031, as stipulated in the terms of reference.

1.2. Terms of Reference as provided by the European Commission

In view of the above and in accordance with Article 29 of Regulation (EC) No 178/2002², the Commission asks EFSA to provide scientific opinions in the field of plant health.

In particular, EFSA is expected to prepare and deliver risk assessments for commodities that shall be listed in the relevant Implementing Acts as "High risk plants, plant products and other objects". Article 42, paragraph 4 and 5, establishes that a risk assessment is needed as a follow-up to evaluate whether the commodities will remain prohibited, removed from the list and additional measures will be applied or removed from the list without any additional measures. This task is expected to be ongoing, with a regular flow of dossiers being sent by Third Countries required for the risk assessment.

Therefore, to facilitate the correct handling of the technical dossiers and the acquisition of the required data for the commodity risk assessment, a format for the submission of the required data for each technical dossier is needed.

In addition, the European Commission asked EFSA to liaise with the EU Member States (MSs) and consult them on this Technical Report.

Furthermore, a standard methodology for the performance of "commodity risk assessment" based on the work already done by Member States and other international organizations needs to be set.

1.3. Interpretation of the Terms of Reference

In January 2018, the European Commission (EC) requested the European Food Safety Authority (EFSA) to provide scientific assistance in standardizing the information requirements for technical dossiers to support demands (from third countries) for import of high risk plants, plant products and other objects as specified in Regulation (EU) No 2016/2031.

In this document EFSA specifies the information and data to be included in the technical dossiers submitted to the European Commission by third country.

With regard to the consultation with MSs, the draft of this Technical Report was circulated to the EFSA Scientific Network for Risk Assessment in Plant health for commenting. The received comments and the EFSA replies are reported in Annex A.

The information and data provided by the applicant, as well further data and information EFSA can search for, will be used by EFSA to perform a commodity risk assessment and to identify the pest³ species for which phytosanitary mitigation measures may be required.

¹ Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC. OJ L 317, 23.11.2016, p. 4–104.

² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

The guidance on how to perform the commodity risk assessment is not included in this Technical Report and it will be delivered, after public consultation, in March 2019.

2. Data and information required to initiate High Risk Plant (HRP) Risk Assessment

The following sections of this document (from section 3 to section 5) outline the data to be provided in the technical dossier submitted by applicants (third countries) to the European Commission on the commodity, pest lists and phytosanitary mitigation measures.

A technical dossier for carrying out the risk assessment referred to in Article 42(4) of Regulation (EU) 2016/2031 on the basis of a demand for import into the Union territory should be submitted to the European Commission. The European Commission shall acknowledge the reception of the technical dossier, examine the completeness of the technical dossier and may ask the applicant for additional information or clarifications, as required by the content and the subject of that application. Where the European Commission concludes that those requirements are fulfilled, it shall transmit the technical dossier to EFSA.

EFSA shall verify that the technical dossier complies with the requirements of this Technical Report and may ask the applicant for additional information or clarifications, as required by the content and the subject of that application. Following that verification, EFSA shall proceed with the commodity risk assessment.

For technical dossiers submitted in the English language, EFSA shall complete the commodity risk assessment within a reasonable period of time. Technical dossiers submitted in another official language of the European Union will first need to be translated into English before transmission by the European Commission to EFSA.

Information should be provided to EFSA in machine readable format. The check-list as specified in Appendix A of this document should be the front page of the technical dossier.

Without prejudice to the validity and completeness checks to be performed by EFSA, the applicant has the full responsibility for the completeness, accuracy and correctness of the data provided to EFSA to perform the assessment. In case additional information is required EFSA may contact the applicant. The compilation of the pest lists should be supported by a literature search (see Appendix B for detailed instructions).

2.1. Confidentiality

The legal framework applicable to EFSA prescribes a high level of transparency as well as the possibility for an applicant to have commercially sensitive information protected insofar as recognised as confidential by EFSA or the European Commission. Award of confidential status implies that in principle this information is not to be disclosed to the public or with a third party. Information deemed to deserve confidential status by EFSA may however be shared with Member States' authorities or the European Commission, or chartered auditors.

The applicant may indicate the information, the disclosure of which might harm the competitive position of a certain third party and which should therefore be treated as confidential.

Requests for confidential treatment should be processed in line with information provided in Annex B of this guidance. Applicants should strive to keep confidentiality claims to a minimum, indicate the elements, bits of data, paragraph or pages claimed confidential and provide verifiable and specific justification for each request. When entire pages are claimed confidential, confidential pages of a

³ According to ISPM n. 5 ((FAO, 2018b) pest is defined as "Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products."

document, in a limited number, they should bear a watermark reading 'CONFIDENTIAL'. If the name of an author is claimed as confidential, it should not be included in the file name and citation.

A list containing all the personal data to be treated as confidential should be included in the technical dossier in order to facilitate sanitisation by EFSA at a later stage.

By no means, information for which the claim of confidentiality has been accepted and awarded should be part of the public access version of the technical dossier.

When submitting additional information, the accompanying cover letter should always indicate whether such additional information contains confidential information, and provide the necessary verifiable justification supporting the request.

Applicants should be aware that submission of a confidentiality claim or request does not ensure acceptance and award of confidential status.

2.2. Public access

In providing the supporting information, the applicant should take into account that all the information provided would potentially be made publicly available by EFSA as background documents to the EFSA Scientific Report, or disclosed in case a request under Regulation EC No 1049/2001⁴, unless the applicant can justify confidentiality in the data provided.

In accordance with Article 38 of Regulation (EC) No 178/2002, EFSA's opinions as well as background information on which opinions are based, excluding confidential information, shall be made accessible to the public. According to the same provision, all documents held by EFSA are subject to Regulation (EC) No 1049/2001 on public access to documents held by EU institutions. Further, environmental information held by EFSA is subject to Regulation (EC) No 1367/2006⁵ on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies.

As a consequence, EFSA may be requested by any citizen and any natural and legal person residing or having its registered office in a Member State of the European Union to grant access to documents submitted in the frame of applications in accordance with the principles, exceptions, conditions and limits laid down in Regulation (EC) No 1049/2001 and Regulation (EC) No 1367/2006. The general principle set out in the above Regulation is that all documents held by EU institutions by default are accessible, unless one or more of the exceptions set out in Article 4 of Regulation (EC) No 1049/2001 apply.

In case of third parties' documents and in accordance with Article 4(4) of the aforementioned Regulation, EFSA consults the third parties concerned with a view to assessing whether an exception to disclosure is applicable, unless it is clear that the document shall or shall not be disclosed.

EFSA's decisions under these Regulations may be challenged before the General Court of the European Union at the conditions set out under Article 263 Treaty on the Functioning of the European Union.

3. Commodity data

To perform a commodity risk assessment, detailed information is required for those plants, plant products and other objects classified as high risk within the meaning of Article 42 of Regulation (EU) 2016/2031. Information must be provided, in the technical dossier submitted by a third country, plant species, commodity type and production methods and areas, as follows:

⁴ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents. OJ L 145, 31.5.2001, p. 43–48.

⁵ Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies, OJ L 264, 25.9.2006, p. 13–19.

- 3.1 Provide scientific name (genus and species), synonyms and if applicable, common name(s) in English, and relevant taxonomic classification, including cultivar or variety if applicable, of the plant (product) to be imported into the EU.
- 3.2 In case of plants for planting (including seeds) indicate the type and age of plants and the growing conditions, as defined in Annex 1 of ISPM 36 (FAO, 2012) (reported in Appendix C of this document). Specify crop, cultivar description of the products or by-products of plant origin to be imported into the EU. Describe the growing media used in production and at the moment of export according to ISPM 40 (FAO, 2017a).
- 3.3 If applicable, indicate whether the plant is grown from certified seeds and/or in a certified nursery. In the case of seeds, specify the type of certification in relation to the absence of the pest(s).
- 3.4 In the case of fruit or vegetables, describe the part/s of the plant, as well as the presentation (i.e. the presence of leaves, sepals, or fruit on the vine, etc.).
- 3.5 In the case of wood, describe the type of wood according to ISPM 39 (FAO, 2017b) (i.e. commodity's type, level of processing, presence/absence of bark, etc.)
- 3.6 In the case of other commodities provide detailed descriptions.
- 3.7 Indicate the period of the year when the commodity is produced and the phenology of the crop (including sowing/planting, flowering, fruiting and harvesting periods).
- 3.8 Describe the general sanitary status and phytosanitary management of the crop in the production area designated for export. If there are differences with other production areas within the country, describe these differences and the reasons for them.
- 3.9 Indicate the intended use of the commodity (i.e., direct distribution to final consumers, repacking for consumption, propagation, milling, transformation, etc.).
- 3.10 Include a map of the exporting country highlighting the production areas and the production areas designated for export.
- 3.11 Indicate how you ensure separation between production areas designated for export and other production areas, if adjacent to the first ones.
- 3.12 Provide the Köppen-Geiger climate classification (sub-group level) relevant for the production areas (<http://koeppen-geiger.vu-wien.ac.at/>)
- 3.13 Attach colour pictures with a brief description of the commodity intended to be exported into EU and of the main stages/steps of production, handling and shipping processes.

4. Identification of all pests potentially associated with the commodity in the exporting country

The applicant should provide lists of all pests potentially associated with the commodity in the exporting country and provide the requested information as indicated below. The compilation of these pest lists by the applicant should be supported by a documented literature search (see Appendix B).

- 4.1 List all the pests potentially associated with the plants species or genus of the commodity in the exporting country supported by evidence (Appendix B).
- 4.2 List all the pests potentially associated with the plants species or genus of the commodity in the exporting country that are EU regulated and provide information as indicated in Table D1 (Appendix D).
- 4.3 List all the pests potentially associated with the plants species or genus of the commodity in the exporting country that are not regulated in the EU, and for these pests provide information as indicated in Table D2 (Appendix D).

- 4.4 For each pest listed in the summary Table D3 (see Appendix D) submit the following information (substantiate this information with the appropriate references, which should be provided together with the technical dossier):
- 4.4.1 Scientific name, synonyms and if applicable, common name(s) in English.
 - 4.4.2 Taxonomic classification, including at least class, order, family, genus, species and information below species level if relevant (e.g. sub-species, pathovar, etc.).
 - 4.4.3 Geographical distribution of the pest in the country, providing if applicable, pest distributions/pest free areas maps for each pest, considering map provided under 3.10 as background layer.
 - 4.4.4 Prevalence of the pest during the season (e.g. percentage of infested plants/fruit during the different phenological stages indicated in paragraph 3.7).
 - 4.4.5 Relevant biological characteristics (i.e., life cycle, association with the pathway, thermal requirements) of the pest.
 - 4.4.6 Main hosts of the pest, including alternate hosts if relevant.
 - 4.4.7 In the case of arthropods and nematodes, for each stage (e.g., egg, larva/nymph, pupa, adult), indicate the part of the plant where it can be found, describe the type of damage. Provide information whether any latent phase or asymptomatic infestation/infection stages are known for the pest species. Indicate also if the arthropod/nematode can be vector of plant disease.
 - 4.4.8 In the case of fungi, bacteria, viruses, phytoplasmas, describe the symptom(s) in the commodity and the part of the plant where it can be found, describe the type of damage. Provide information whether any latent phase or asymptomatic infestation/infection stages are known for the pest species.
 - 4.4.9 In the case of any other living organism (e.g. parasitic plants), describe their association with the commodity.
 - 4.4.10 Indicate the impact caused by the pest on the commodity and/or relevant hosts other than the commodity.
 - 4.4.11 If available provide pest risk assessment(s).

Please note that the applicant is invited to submit any additional information or evidence that is considered useful in supporting the risk assessment (e.g. list of all pests known to use the plant species or genus of the commodity as hosts at the global level, records of interceptions on the exported commodity, etc.).

Please also note that EFSA reserves the right to request the information referred to in points from 4.4.1 to 4.4.11 and in section 5, also for other pests than those listed in Table D3 (e.g., other pests listed in Table D1 and/or Table D2 or other pests found by EFSA in its review).

5. Data on phytosanitary mitigation measures

- 5.1 Describe phytosanitary mitigation measures (including the ones intended to be applied when exporting the commodity into the EU) of the commodity and their effectiveness, supported by evidences (i.e. probit 9, average survival time, etc.) following Appendix E.
- 5.2 Indicate phytosanitary regulations and inspection systems related to the crop of interest or associated quarantine pests in the country of origin.
- 5.3 Describe surveillance and monitoring systems of the pests associated with the commodity as detailed as possible (e.g. sampling and inspection strategies, frequencies, intensities, diagnostic protocols, etc.).
- 5.4 Indicate volume, frequencies and seasonal timing planned for export to the EU.

- 5.5 Describe the post-harvest processes and transport system (from farm to processing and from processing to point of export), including type of packaging material, size of packaging, shipping capacity. Likewise, indicate temperature and relative humidity of the containers, if applicable.

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Appendix A – Check-list of the data provided in the technical dossier

This check-list should be the front page of the technical dossier. The column in blue should be filled by EFSA.

	Provided	Not provided	EFSA agrees	EFSA comments
3 COMMODITY DATA				
3.1 Taxonomic information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.2 Plants for planting specification (ISPM 36 – FAO, 2012)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.3 Seeds specification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.4 Fruit and vegetable specification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.5 Wood specification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.6 Other commodities specification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.7 Production period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.8 Phytosanitary status and management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.9 Intended use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.10 Production area	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.11 Separation of production areas				
3.12 Climatic classification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.13 Pictures and description	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4 PESTS LIST				
4.1 List of all the pests potentially associated with the commodity plant species or genus in the exporting country	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.2 List of EU regulated pests (Table D1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.3 List of non-regulated pests (Table D2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4 Summary table of relevant pests associated with the commodity (Table D3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Details of the literature search according to Appendix B	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
OPTIONAL- Additional information or evidence (e	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Data for each pest of Table D3				
4.4.1 Scientific name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.2 Taxonomic classification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.3 Geographical distribution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.4 Prevalence of the pest during the season	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.5 Biology of the pest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.6 Main hosts				
4.4.7 Arthropods and nematodes description	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.8 Pathogens description	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.9 Other living organisms description	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.10 Impact of the pest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.11 Information from other pest risk assessment(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5 DATA ON PHYTOSANITARY MITIGATION MEASURES				
5.1 Description of phytosanitary mitigation measures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.2 Description of phytosanitary regulations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.3 Description of surveillance and monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.4 Trade volumes and frequencies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.5 Description of post-harvest procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Appendix E tables				

Information required for dossiers to support demands for import of high risk plants

Table E1 - Details of pesticide treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Table E2 - Details of other treatments/measures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Table E3 - Calendar including relevant crop phenology data, pest presence in the crop and timing of treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Table E4 - Assessment of the overall efficacy of phytosanitary mitigation measures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Appendix B – Explanatory note on literature search

A literature search involves the development of a search strategy and the identification of information sources to retrieve relevant information. The appropriate sources of information should be searched in a structured manner, and the search strategies and information sources used should be documented and reported.

Sources of information

Applicants should make reasonable efforts to locate all the sources that yield relevant information, and provide the rationale behind the selection of the sources.

The search should consider sources of scientific, technical and grey literature. Bibliographic databases, repositories, websites of organizations, websites of conferences, tables of contents of specific journals, etc. might be used in order to retrieve journal articles, books, reports, conference abstracts, datasheets, maps, and other types of information relevant to build the list of pest associated to the commodity in the exporting country.

Sources of information with a broader coverage (e.g. Web of Science, CAB Abstracts) may need to be supplemented with sources published in the specific geographic region relevant for the applicant.

Developing search strategies

Applicants shall design and develop appropriate search strategies (i.e. search terms and their combinations). The search strategies should be designed to be sensitive in order to retrieve as much potentially relevant information as possible. This usually involves using as many synonyms and related terms as useful to represent a concept (e.g. scientific name, and common names of a commodity) and combining free-text with controlled vocabulary when available. The combination of the terms using proximity or Boolean operators (when available) should be also designed to maximize the retrieval of relevant information.

The search strategies should be also adapted to the characteristics, and requirements of each source of information. The adaptation might include, among others, the search syntax or the language used for the search terms.

Applicants should follow the recommendations of the "[Technical Manual for Performing Electronic Literature Searches in Food and Feed Safety](#)" (Glanville et al., 2014) when performing the searches and documenting its outcome.

Reporting the search in the technical dossier submitted by third countries

In order to promote transparency and allow the evaluation and replication of the process, the search methodology and its results must be documented and reported in detail.

For database searches, the following information should be reported for each result:

- The name of the database and the service provider used;
- The URL of the database (internet address);
- The justification for choosing the database;
- The date on which the search was conducted;
- The date of the most recent update of the bibliographic database (when available);
- The date span of the search;
- Any limits applied to the search (e.g. publication types)
- The complete search strategy or strategies used (as run in the database), and the number of results retrieved.

For resources other than databases, the following information should be reported for each result:

a) For websites or tables of contents of journals:

- The name of the resource (i.e. website name, journal name in case of searching in a specific table of content).
- The URL of the resource (internet address);
- The justification for choosing the website or journal:
- The date on which the search was conducted, and the date range of the search, or the dates, volumes and issues searched in the case of table of contents.
- The method of searching (e.g. browsing, using the search engine included in the website, scanning in the case of tables of contents).
- The search terms used to search, and the number of relevant records retrieved.

b) For reference lists:

- The bibliographic details of the documents whose reference lists were scanned;
- The number of relevant bibliographic references retrieved.

Reporting the results of the search in the technical dossier submitted by third countries

A full list of references retrieved from the literature search as well as a list of references used to develop the technical dossier should be provided in English and in machine readable format.

Copies of the full-text documents (or relevant sections of large documents) used for developing the technical dossier should be provided preferably in English; however, full-text documents (or relevant sections of large documents) used for developing the technical dossier in other official EU languages would also be accepted. Documents in non-EU languages should be translated preferably into English, or in other official language of the EU, before submission to the European Commission.

Copies of the full-text documents not used for developing the technical dossier do not need to be submitted with the technical dossier. However, the applicants should be prepared to provide them later if requested by EFSA.

Ensuring that copyright, licensing and data protection issues concerning the information included in the technical dossiers have been fully satisfied remains the responsibility of the applicant. The applicant should consult the competent national copyright licensing authority(ies) for guidance on purchasing copyright licenses to reproduce copyright publications which must be submitted within the technical dossier. It should be noted that the applicant remains the sole legal or natural person responsible and liable for obtaining all necessary authorisations and rights to use, reproduce and share the publications submitted in their applications. Under no circumstances may EFSA be kept accountable for breaches of intellectual property rights infringed by applicants by including the relevant datasets or information in the technical dossier.

Appendix C – Classification of plants for planting

In Annex 1 of ISPM 36 (FAO, 2012) nine types of plants for planting (excluding seeds) are distinguished ranked from lowest to highest pest risk:

1. meristem tissue culture
2. in vitro culture
3. budwood/graftwood
4. unrooted cuttings
5. rooted cuttings
6. root fragments, root cuttings, rootlets or rhizomes
7. bulbs and tubers
8. bare root plants
9. rooted plants in pots

Furthermore, pest risk may increase with plant age, as older plants have been exposed to potential pests for longer.

Examples of growing conditions ranked from lowest to highest pest risk:

1. growth chamber
2. greenhouse
3. screen house
4. field grown in containers (pots, tubs etc.)
5. field grown
6. plants collected from the wild

Appendix D – Steps to select pests that may require phytosanitary mitigation measures

The sequence of steps described below should be supported by a literature search (Appendix B).

1. List in the Table D1 the pests that are EU regulated and known to use the plant species or genus of the commodity as host⁶ (e.g., using the CABI, online, EPPO online), providing the following information for each pest:
 - **Pest species** (Latin name)
 - **Taxonomic information (class, order, family)** (e.g. in case of *Thaumatotibia leucotreta* : Insecta, Lepidoptera, Tortricidae)
 - Provide a **pest status** statement, for example referring to ISPM 8 (FAO, 2017c) and supported by the appropriate evidence
 - If applicable, provide evidence for **pest free area** according to ISPM 4 (FAO, 2017d)
 - Indicate the **regulatory status** of the pest in your country. E.g. regulated quarantine pests, regulated non-quarantine pests, pests considered for official control, pests that require evaluation for regulatory action as well as common non-regulated pests.
 - **Can the pest be associated with the commodity (irrespective of any treatment)?**: Applicant should provide evidence if the pest can or cannot be associated with the commodity
 - **Identify pests that may need phytosanitary mitigation measures**: present in the country as well as clarify whether pest is associated with the commodity (copy these species to Table D3)

Table D1 – List of EU regulated pests, present in the applicant third country and known to use the plant species or genus of the commodity as host

Pest species	Taxonomic information	Pest status in the applicant third country	Pest free area(s)	Evidence and uncertainty on pest status and pest free area(s)	Regulatory status in the applicant third country	Can the pest be associated with the commodity?	Evidence and uncertainty on association with the commodity	Pest for which phytosanitary mitigation measures may be required
						<input type="checkbox"/>		<input type="checkbox"/>
						<input type="checkbox"/>		<input type="checkbox"/>
						<input type="checkbox"/>		<input type="checkbox"/>
						<input type="checkbox"/>		<input type="checkbox"/>
						<input type="checkbox"/>		<input type="checkbox"/>

⁶ The list of pest associated with the commodity in your country should be obtained and documented by a literature search (see Appendix D).

2. List in Table D2 all the other pests present in your country associated with the plants species or genus of the commodity (excluding the pests already listed in Table D1), according to Table D2 and provide the information indicated below. The list of pests associated with the commodity in your country should be obtained and documented by a literature search conducted following the Appendix B including search of scientific and grey literature and international database as e.g., EPPO, online and CABI, online.

- **Pest species** (Latin name)
- **Taxonomic information (class, order, family)** (e.g. in case of *Thaumatotibia leucotreta* : Insecta, Lepidoptera, Tortricidae)
- **Status in the EU:** Absent (A), Restricted distribution under official control (R), Present (P). Check and provide evidence (e.g. EPPO, online, CABI, online data bases)
- If applicable, provide evidence for **pest free area**
- Indicate the **regulatory status** of the pest in your country
- **Can the pest be associated with the commodity (irrespective of any treatment)?:** check and provide evidence
- **Does the pest have impact in your country?:** check and provide evidence on the level of impact⁷
- **Pest of potential risk for EU** - pests that fulfil the following criteria: it is absent in EU or it has restricted distribution under official control + the pest is associated with the commodity + it has or can have potential impact (copy these species to Table D3)

Table D2 – List of pests not regulated in the EU, present in the applicant third country and known to use the plant species or genus of the commodity as host

Pest species	Taxonomic information	Status in EU	Pest free area(s)	Evidence and uncertainty on pest status and pest free area(s)	Regulatory status in applicant third country	Can the pest be associated with the commodity?	Evidence uncertainty on association with the commodity	Does the pest have impact in applicant third country	Evidence and uncertainty on the level of impact ⁵	Pest of potential risk for EU
						<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
						<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
						<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
						<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>

⁷ If the pest has an impact in your country please describe the impact and the symptoms and provide reference; if you consider the pest does not have an impact in your country please explain why and provide reference if available.

Table D3 – Summary table of pest species, present in the applicant third country, associated with the commodity and that may have a potential risk for EU for which technical data will be requested in Appendix E.

For the pest species associated to the commodity and that may have a potential risk for EU (selected from tables D1 and D2), provide the following information:

- **Pest species** (Latin name)
- **Regulated pest in EU:** indicate if the pest is a quarantine pest in the EU according to the current plant health legislation⁸.

Pest species associated with the commodity	Regulated pests in EU
	<input type="checkbox"/>

For each of the pests in Table D3 provide the data indicated in point 4.4 of this document.

⁸ Consult the latest legislation current at the moment of the application.

Appendix E – Evidence to support the assessment of the efficacy of phytosanitary mitigation measures

Applicant should provide, using Tables E1 and E2, the technical data supporting the evaluation of the efficacy of the phytosanitary mitigation measures for each of the pests listed in Table D3. Please provide, using Table E3 as template (this template may need to be adapted for different commodities), a calendar where pest presence and mitigation measure/s are presented. It is essential that the estimation of efficacy provided by the applicant is supported by scientific and technical evidence (i.e., probit 9, average survival time, etc.).

Then use Table E4 for summarising the overall efficacy for each of the pests listed in Table D3, emphasizing the likelihood of pest-freedom of the commodity and its associated uncertainties. Include a clear justification and provide supporting evidence where appropriate.

Table E1 - Details of pesticide treatment

Pesticide/s used (active substance/s)	Scientific name of the target pest species	Targeted life stage of the pests	Timing of the treatment ⁹	Dose in kg/ha used for each treatment ¹⁰	Use the information reported in the officially approved label	Restrictions if any	Estimation of efficacy ¹¹	Evidence for the efficacy ¹²
					<ul style="list-style-type: none"> • Application type • Application time • Time period for which a treatment remains effective • Life stages affected 			
					<ul style="list-style-type: none"> • 			

⁹ Indicate month and production phase (pre-harvest, harvest, post-harvest); provide a calendar where pest presence and treatment/s are presented (see Table E3).

¹⁰ Specify if the dose refers to the active substance or to the commercial product.

¹¹ Provide the specific value for efficacy of the pesticide treatment to control the target plant species on the commodity if available, or indicate at least one of the following classes adapted from Table 2 of EFSA 2017: Extremely high (>95%), Very high(90–95%), High (66–90%), Medium (33–66%), Low (10–33%), Very low (5–10%), Extremely low (<5%).

¹² Please list here the evidence supporting the estimation of efficacy provided by the applicant:e.g., Plant Protection Products labels, papers, technical reports, experimental data, grey literature, etc. Copy of such evidence should also be provided as attachment to the technical dossier. For more details on the required information and evaluation of phytosanitary mitigation measures see EFSA PLH Panel, 2012.

Table E2 - Details of other mitigation measures (other than pesticides)

Measures used ¹³	Scientific name of the target pest species	Targeted life stage of the pests	Timing of the treatment ¹⁴	Details on the measure used	Reference to a protocol standards	Restrictions if any	Estimation of efficacy ¹⁵	Evidence for the efficacy ¹⁶
				e.g. temperature	e.g. ISPM 15 (FAO, 2018a)			
					•			
					•			

¹³ Refer to the check-list of Risk Reducing Options (EFSA PLH Panel, 2018)

¹⁴ Indicate month and production phase (pre-harvest, harvest, post-harvest); provide a calendar where pest presence and treatment/s are presented (see Table E3).

¹⁵ Provide the specific value for efficacy of the measure to control the target pest species on the commodity if available, or indicate at least one of the following classes adapted from Table 2 of EFSA 2017: Extremely high (>95%), Very high(90–95%), High (66–90%), Medium (33–66%), Low (10–33%), Very low (5–10%), Extremely low (<5%).

¹⁶ Please list here the evidence supporting the estimation of efficacy provided by the applicant: e.g., Plant Protection Products labels, papers, technical reports, experimental data, grey literature, etc. Copy of such evidence should also be provided as attachment to the technical dossier. For more details on the required information and evaluation of phytosanitary mitigation measures see EFSA PLH Panel, 2012.

Table E3 - Example of a calendar including relevant crop phenology data, pest presence in the crop and timing of treatment

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Crop phenology			Bloom					Mature fruit				
Presence of target stage	A d u l t s											
Treatments								Mass trapping				
	Sterile Insect Technique											
								Pesticide X				
	Cultural/Biological control: cover crops											
	Sanitation									Sanitation		

Table E4 - Assessment of the overall efficacy of phytosanitary mitigation measures (combination of pesticide and non-pesticide measures).

Pest species	Estimation of the overall efficacy of phytosanitary mitigation measures ¹⁷	Associated uncertainties	Justification (reasoning and evidence) for the overall efficacy ¹⁸

¹⁷ Provide for each pest associated with the commodity a specific estimation of the overall efficacy of the phytosanitary mitigation measure applied, if available, or indicate at least one of the following classes adapted from Table 2 of EFSA 2017: Extremely high (>95%), Very high(90–95%), High (66–90%), Medium (33–66%), Low (10–33%), Very low (5–10%), Extremely low (<5%).

¹⁸ Please summarise here the evidence and reasoning supporting the estimation of efficacy provided by the applicant :e.g., Plant Protection Products labels, papers, technical reports, experimental data, grey literature, etc. Copy of such evidence should also be provided as attachment to the technical dossier. For more details on the required information and evaluation of phytosanitary mitigation measures see EFSA PLH Panel, 2012.

Annex A – Member States’ comments on the draft EFSA Technical Report

Annex B – List of elements of the technical dossier for which confidentiality treatment is requested by the applicant

Annexes A and B can be found in the online version of this output (in the “Supporting information section”): <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2018.EN-1492>